Validation of AHRQ's Patient Safety Indicator for Accidental Puncture or Laceration

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Abstract

Objectives: This study examined whether clinical evidence in medical records confirms ICD-9-CM diagnoses that identify the Patient Safety Indicator (PSI) accidental puncture or laceration (APL), and examined the utility of procedure codes in identifying patients who suffered an APL. **Methods**: Validation results were based on a retrospective medical record review of 67 inpatients from the year 2000 in New York State with ICD-9-CM codes corresponding to APL. Secondary procedure codes of New York inpatients during 2001 were examined to identify patients suffering punctures and lacerations who were not captured by the PSI. **Results**: Clinical conditions represented by ICD-9-CM codes used in the PSI were frequently not present in the records of the 67 patients. Cases of APL that were missed by the PSI were identified using procedure codes. **Conclusions**: Not all of the patients identified by the PSI meet the intent of the indicator. The PSI also misses cases of APL by failing to use procedure codes in the algorithm.

Introduction

Various types of algorithms that identify complications of care and adverse events in hospitalized patients have been developed using administrative data. These efforts have included algorithms identifying specific procedures or conditions[1–9] and algorithms that identify broader groups of patients.[10–17] The Complications Screening Program (CSP) by Iezzoni et al.[11] and the Patient Safety Indicators (PSIs) by Miller et al.[18] have significantly contributed to the most recent set of inpatient quality indicators, developed by Stanford University and the University of California with a grant from the Agency for Healthcare Research and Quality (AHRQ).[19] These new AHRQ Quality Indicators identify a number of complications of care or adverse events and have been made available to researchers.[20]

There has been limited validation of administrative data algorithms. The CSP algorithms were evaluated by Iezzoni and colleagues[21–24] while the AHRQ PSIs were evaluated as part of the development process.[19] Several issues were raised by the AHRQ physician consultants during the development of the accidental puncture or laceration PSI, including the contribution of trauma patients to events identified by the PSI. A second concern was that, while the intent of the APL PSI is to identify all punctures and lacerations that occur in the inpatient setting, only the most serious adverse events would be captured with the diagnosis codes selected**.** Researchers involved in the development of the PSI measures and the AHRQ have called for additional review and validation of these indicators[19, 25] as

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researchers have begun to apply the indicators to their work.[26–28] In this paper, we present findings of our analysis and validation of the indicator intended to identify cases of accidental puncture or laceration (APL) that occur in the hospital after a procedure.

Specifically, the purposes of the study are to use medical record reviews to (1) validate the occurrence of in-hospital APLs associated with the PSI for APL, and (2) investigate the occurrence of in-hospital APLs associated with minor lacerations or punctures. We also examine procedure codes of cases captured by the PSI to determine if any changes to the algorithm can be made to identify additional events. The use of procedure codes used to identify events are similar to the methodology used by Iezzoni for CSP 17, procedure-related perforation or laceration,[11] and the AHRQ experimental PSI, suture of laceration.[19]

Methods

Data source

The AHRQ PSI program, Version 2.1, Revision 1, May 2003,[20] contains modules that define denominator and numerator events, calculate overall observed rates, and calculate risk-adjusted rates of patient safety events. These programs were applied to data from the New York State inpatient hospitalization administrative data system, the Statewide Planning and Research Cooperative System (SPARCS), for discharges in 2001.

Case identification

Measures of Patient Safety Based on Hospital Administrative Data—The Patient Safety Indicators, Technical Review 5,[19] defines the denominator for the APL indicator as all medical and surgical discharges defined by specific diagnosis related groups (DRGs), excluding obstetrical patients in medical diagnostic category (MDC) 14. Numerator events are defined as medical and surgical discharges with International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes[29] for accidental puncture or laceration in any secondary diagnosis field.

Data analysis

The validation sample is based on the New York State inpatient adverse event report system, New York Patient Occurrence Reporting and Tracking System (NYPORTS), which captures a variety of adverse events. Rates of inpatient hospital adverse event reporting were calculated, where the total number of events reported to NYPORTS was in the numerator, and the total number of inpatient discharges was in the denominator. New York State hospitals were ranked by NYPORTS reporting rate, with a sample of high, moderate, and low reporting hospitals selected. Records of inpatients admitted with APL as a secondary diagnosis in 2000 were extracted from SPARCS for these sample hospitals. While the APL PSI includes cardiac patients, our validation sample did not include

cardiac patients. New York State has several adverse event reporting systems, including the New York State Adult Cardiac Reporting System and NYPORTS. The validation sample used for this analysis was selected for inpatient adverse events which are reportable to NYPORTS and excludes cardiac patients because these events are reportable to New York State Adult Cardiac Reporting System.

Records for 67 patients who were identified using the AHRQ PSI definition for APL were provided to an independent review agent, the Island Peer Review Organization (IPRO), for medical chart review. IPRO used registered nurses to conduct retrospective medical record reviews using a standard validation review instrument to determine if a reportable event occurred. The validation review instrument was used to collect information corroborating the diagnosis of APL, confirming the timing of the event (present at admission or developed in the hospital), confirming the severity of the event (penetration of lumen or removal of organ versus laceration or penetration of serosal or muscular layers), and ascertaining if the patient suffered trauma. The validation review summaries were analyzed to determine if the potential APL, as defined using the AHRQ APL definition, was an event that occurred during the index hospitalization.

Primary and secondary procedure codes of cases captured by the PSI were also examined to determine if accidental puncture or laceration patients with particular primary procedures could be identified using specific secondary procedure codes.

Analytic approach

Numerator events were validated using medical record reviews. The proportion of cases confirmed as in-hospital APL events, the proportion of cases not confirmed due to the timing of the diagnosis, the proportion of cases not confirmed due to lack of clinical evidence in the medical record, and the proportion of trauma cases were calculated. In addition, the proportions of confirmed cases with a minor puncture or laceration were identified.

The number of numerator and denominator events identified with the PSI and the rate of APL events were calculated. Numerator and denominator counts and the APL rate were also calculated after patients who were identified as being erroneously captured by the PSI were removed. The number of patients with secondary procedure codes indicating puncture or laceration for specific primary procedures who were not captured by the PSI was also calculated.

Results

Using the original algorithm for the PSI and applying it to 2001 inpatient discharges in New York State, we identified 4,643 numerator events and 1,947,441 patients in the denominator, which is 2.4 accidental lacerations or punctures per 1,000 discharges (Table 1).

The PSI erroneously identifies cases that have accidental puncture or laceration diagnosis codes in the principal diagnosis position. This occurs when a

patient has a primary diagnosis of accidental puncture or laceration and a secondary diagnosis of accidental puncture or laceration in the same record. Because the intent of the indicator is to identify cases that occur after admission,

Table 1. Accidental puncture or laceration (APL) events based on revised exclusions, New York State, 2001

Exclusions*	No. of records with APL	Risk pool for APL†	APL rate per 1,000 discharges
PSI algorithm	4,643	1,947,441	2.4
Eliminate 1st DX=APL	4,408	1,946,862	2.3

*PSI = Patient Safety Indicators; 1st = principal; DX = diagnosis.
†Risk pool definition based on PSI inclusion and exclusion algorithm.

these cases were eliminated from the PSI. The revised definition yields 4,408 events from 1,946,862 at-risk patients, which is 2.3 accidental lacerations or punctures per 1,000 discharges. This rate of 2.3 per 1,000 discharges is lower than recently published estimates using the AHRQ PSIs. Romano et al. established an accidental puncture and laceration rate of 3.24 per 1,000 discharges using data from the 2000 Nationwide Inpatient Sample.[28]

Table 2 indicates that for the 67 cases in the validation dataset, two patients (3.0 percent) did not meet the definition of an APL because they did not have clinical evidence in their charts indicating the presence of an accidental puncture or laceration; and two patients (3.0 percent) did not meet the intent of the APL PSI definition because they had an accidental puncture or laceration present at admission. The medical chart review also revealed three trauma cases (4.5 percent), two of which had the puncture or laceration caused by the trauma prior to admission and one that had the complication after admission. Ten (14.9 percent) of the cases had an accidental laceration or puncture coded, but the review indicated that the injuries were not serious. These complications involved either a cut or tear of the muscle or serosal layers, and did not include any penetration of lumen or removal of organs. The remaining 50 cases (74.6 percent) appeared to be serious complications of care.

Table 2. Validation of APL events, New York State, 2000

Data characteristics	N	%
Validation set	67	–
Non-APL cases	2	3.0
Serious cases	50	74.6
Not serious cases	10	14.9
Trauma	2	3.0
Trauma and PSI	1	1.5
Readmits	2	3.0

Lacerations and punctures are captured in the PSI using diagnosis codes. It is also possible to identify lacerations and punctures using secondary procedure codes. (See Table 3 for secondary procedure codes indicative of accidental puncture and injury for select principal procedures.)

Table 3. Secondary diagnosis or procedure codes for identifying potential accidental puncture or laceration patients

Injury types	ICD-9-CM codes
Bladder injury associated with hysterectomy	57.81 - Suture of laceration of bladder 57.89 - Other repair of bladder: bladder suspension, not elsewhere classified; cystopexy NOS; repair of old obstetric laceration of bladder
Bowel injury associated with cholecystectomy	46.71 - Suture of laceration of duodenum 46.73 - Suture of laceration of small intestine, except duodenum 46.75 - Suture of laceration of large intestine 46.79 - Other repair of intestine
Abdominal injury associated with lysis of peritoneal adhesions	569.83 -Perforation of intestine 07.44 - Repair of adrenal gland 39.3 - Suture of vessel 39.59 - Other repair of vessel 41.95 - Repair and plastic operations on spleen 44.61 - Suture of laceration of stomach 44.69 - Other repair of stomach: Inversion of gastric diverticulum 46.71 - Suture of laceration of duodenum 46.73 - Suture of laceration of small intestine, except duodenum 46.75 - Suture of laceration of large intestine 46.79 - Other repair of intestine 48.71 - Suture of laceration of rectum 48.79 - Other repair of rectum: repair of old obstetric laceration of rectum; Inversion of gastric diverticulum 50.6 - Repair of liver 51.71 - Simple suture of common bile duct 51.79 - Repair of other bile ducts: closure of artificial opening of bile duct NOS; Suture of bile duct NOS 51.91 - Repair of laceration of gallbladder 52.95 - Other repair of pancreas: fistulectomy of pancreas; simple suture of pancreas 54.63 - Other suture of abdominal wall: suture of laceration of abdominal wall 54.64 - Suture of peritoneum: secondary suture of peritoneum 54.72 - Other repair of abdominal wall 54.73 - Other repair of peritoneum: suture of gastrocolic ligament

Table 3. Secondary diagnosis or procedure codes for identifying potential accidental puncture or laceration patients, cont.

Injury types	ICD-9-CM codes
	54.74 - Other repair of omentum: epiplorrhaphy; graft of omentum; omentopexy; reduction of torsion of omentum 54.75 - Other repair of mesentery: mesenteric placation; mesenteropexy 55.81 - Suture of laceration of kidney 55.89 - Other repair of kidney 56.82 - Suture of laceration of ureter 56.89 - Other repair of ureter: graft of ureter; replacement of ureter with ileal segment implanted into bladder 57.81 - Suture of laceration of bladder 57.89 - Other repair of bladder: bladder suspension, not elsewhere classified; cystopexy NOS; repair of old obstetric laceration of bladder
Abdominal injury associated with nephroureterectomy	See codes for abdominal injury associated with lysis of peritoneal adhesions
Spinal injury associated with lumbar surgery	03.59 - Other repair and plastic operations on spinal cord structures: diastematomyelia; spinal bifida NOS; spinal cord NOS; spinal meninges NOS; vertebral arch defect

Note: Five-digit codes are diagnosis codes; all others are procedure codes.

Table 4 presents counts of events that appear to be accidental punctures or lacerations based on analysis of the primary and secondary procedure codes for patients who had one of five select primary procedures. For instance, for patients who underwent a hysterectomy as the principal procedure, the table shows that 194 patients with bladder injuries were captured by the PSI, and 73 (27.3 percent) inpatients had these injuries during 2001 in New York State and were not captured by the PSI. Cholecystectomy patients who suffered bowel injuries were not captured by the PSI 20.8 percent of the time. For patients undergoing lysis of peritoneal adhesions who suffered abdominal injuries, 47.4 percent were not captured by the PSI. A total of 53.8 percent of nephroureterectomy patients developing abdominal injuries were not captured by the PSI, and 19.6 percent of lumbar surgery cases with spinal injuries were not identified by the PSI.

Table 4. Potential laceration or puncture adverse events associated with five principal procedures

Procedures	Events captured with PSI definition		Events not captured with PSI definition	
	N	%	N	%
Bladder injuries caused by hysterectomy	194	72.7	73	27.3
Bowel injuries caused by cholecystectomy	61	79.2	16	20.8
Adnominal injuries caused by lysis of peritoneal adhesions	91	52.6	82	47.4
Abdominal injuries caused by nephroureterectomy	24	46.2	28	53.8
Spinal injuries caused by lumbar surgery	74	80.4	39	19.6

Discussion

With the publication of the Institute of Medicine's recent report, *To Err Is Human: Building a Safer Health System,*[30] there has been an emphasis on identifying adverse events that occur in the inpatient setting as a means of informing hospitals of the extent of various problems, and as a means of measuring the impact of efforts to improve quality. This is a difficult undertaking because it is expensive to create databases for this purpose and because existing administrative databases that were created for other purposes are limited in their ability to supply this information. AHRQ has developed Patient Safety Indicators to be used with administrative data based on the pioneering efforts of Iezzoni and colleagues as well as work generated from grants to Stanford University and the University of California at San Francisco.

AHRQ has published the PSIs, which include commentary by medical and surgical specialists who consulted on algorithm development.[19] Several issues were raised by the panels with regard to the accidental puncture or laceration PSI, including the contribution of trauma patients to events identified by the PSI. A second concern of the physician reviewers was that, while the intent of the APL PSI is to identify all punctures and lacerations that occur in the inpatient setting, it is possible that only the most serious adverse events would be captured with the diagnosis codes selected. The results of our validation sample indicate that both of these issues affect the PSI results.

The validation results indicate that the PSI does not include criteria that are explicit enough to exclude patients with a primary diagnosis of accidental puncture or laceration. Two cases (3 percent) in the validation sample had a principal diagnosis of accidental puncture or laceration and were readmissions for a puncture or laceration. These patients do not meet the indicator's intent, which is to identify occurrence of an accidental puncture or laceration during the index

admission. Changing the algorithm and applying it to New York State discharges in 2001 yields 4,408 events from 1,946,862 at-risk patients, which is 2.3 accidental lacerations or punctures per 1,000 discharges, compared to the 2.4 accidental laceration or punctures per 1,000 discharges resulting from the original algorithm (Table 1). This deficiency in the algorithm could be addressed by excluding accidental puncture or laceration codes from the primary diagnosis field.

A second finding of the validation sample is that trauma patients are being captured by the PSI. While our sample of trauma cases (three cases, 4.5 percent) is too small to draw definitive conclusions, it is a concern that two out of the three trauma cases that were evaluated were not accidental punctures or lacerations; the injuries were suffered prior to hospitalization. While AHRQ recognized this issue during algorithm development, and chose to include these patients, the benefit of identifying a small number of APLs in trauma patients may be outweighed by including events in the numerator that are not actual APLs. If trauma patients are going to be identified and eliminated from the PSI, the definition of a trauma patient specified in the PSI documentation appears to be too broad (a single ICD-9-CM code from selected diagnoses in the 800–958 range or one of several DRGs). A more restrictive definition that requires at least two ICD-9-CM diagnosis codes in the 800–956 range or the principal diagnosis in this range would be more appropriate to capture true trauma cases. Using this more restrictive definition of trauma, we identified 128 cases in the APL PSI for New York State in 2001, 2.8 percent of the total events identified for this period.

An additional concern raised by the medical consultants during the development of the PSI was that the algorithm may capture only the most serious adverse events and that moderately injured patients or patients with minor injuries will go undetected. This is a concern because the intent of the PSI is to capture all events occurring in the inpatient setting, and the diagnosis codes used may only capture the most serious events. If quality improvement initiatives are to be developed based on events captured in the PSI, surgeons causing minor or moderate injuries may not be identified by the APL PSI and will not be targeted for quality improvement. Using a simple definition of severity where puncture of a lumen or removal of an organ represents a serious event, and puncture or laceration of the muscle or serosal layer is considered a minor event, the validation sample results indicate that a small number of cases (10 or 14.9 percent) are not serious complications. The ascertainment of severity was based on review of the medical chart documentation, and, unfortunately, it does not appear that serious and minor events can be differentiated using diagnosis and procedure codes recorded in the administrative record. Based on this finding, patients with minor injuries captured by the PSI algorithm cannot be easily identified with administrative data, but users of the PSI should be aware of the proportion of cases that may not be serious events.

The validation results reveal that the diagnosis codes used to identify punctures and lacerations are accurate, with 97.0 percent (65) of the cases having an indication of an injury in the medical chart, but not all of these cases meet the

intent for the PSI. A small proportion of the events (3.0 percent) were readmissions that can be excluded with a minor change to the algorithm. The concerns of the medical consultants involved in the development of the PSI—that only the most serious adverse events would be captured with the diagnosis codes used in the PSI—appear to be borne out by this analysis. Only 14.9 percent of the events did not appear to be serious injuries, and 4.5 percent involved trauma cases. It is unclear whether identification of all punctures and lacerations is necessary to facilitate quality improvements in the inpatient setting, or if it is sufficient to capture the most serious cases. It is likely that many of the trauma patients identified by the indicator suffered injuries outside of the control of medical personnel. Eliminating cases that did not have an indication of puncture or laceration in their chart (3 percent), readmissions (3 percent), and trauma cases (4.5 percent) leaves 88.5 percent of the cases identified by the PSI as cases of injury that may be appropriate for hospitals to identify and examine in order to make quality-of-care improvements.

These validation results are generally applicable to the patients identified by the APL PSI, except for cardiac patients. Our sample did not include cardiac patients, and these patients make up approximately 23 percent of the patients identified by the PSI in New York State during 2001. Additional validation studies that include cardiac patients should be conducted to determine if these results are applicable to cardiac patients.

The APL PSI relies on a single diagnosis code and 10 external cause-of-injury codes (E-codes) to identify adverse events. It is possible to identify punctures and lacerations using procedure codes, as evidenced by Iezzoni's CSP 17, procedure-related perforation or laceration,[11] and the AHRQ's experimental PSI, suture of laceration.[19] CSP 17 uses four diagnosis codes in a secondary field and 16 procedure codes in a secondary field to identify patients. The AHRQ experimental PSI uses only procedure codes in a secondary field to identify patients. The approach taken in this analysis uses procedure codes in a secondary position, but we also limited the patients included in the study to those having specific secondary procedures associated with certain primary procedures. Table 3 lists a proposed set of secondary procedure codes that can be used to identify puncture and laceration in patients undergoing specific primary procedures.

The APL PSI captures patients who have many different primary procedures. One of the primary procedures that occurs often in this PSI is hysterectomy. Hysterectomies are associated with certain operative complications,[31, 32] including accidental laceration of other organs, particularly the bladder. When we examined the records captured by this PSI using New York State discharge data from 2001 and selected the subset with hysterectomy as the primary procedure, we found 472 hysterectomies with 194 bladder lacerations (ICD-9-CM procedure codes 57.81, suture of laceration of bladder or 57.89, other repair of bladder) in any secondary procedure field. Clearly, a large proportion (41 percent) of the hysterectomies was captured by the PSI because of accidental bladder laceration, as indicated by a secondary procedure. To determine if the PSI is capturing all of the bladder lacerations occurring in hysterectomies, we examined how many

records with a primary procedure code of hysterectomy had a secondary procedure of bladder laceration in the absence of the PSI definition for accidental puncture or laceration. Using data from New York State, 2001, 267 bladder lacerations were identified in patients undergoing hysterectomies, and 73 of the 267 (27.3 percent) were not captured by the PSI. For this primary procedure, the discharge data can be examined to identify the particular sites of accidental puncture or lacerations by reviewing secondary procedure fields. This allows us to estimate the completeness of the indicator for this particular primary procedure.

This method of identifying APLs may not accurately identify accidental punctures or procedures in all cases, because it may be possible that a patient has comorbid conditions that require additional secondary procedures, in addition to the principal procedure, as part of patient treatment. Our intent is not to definitively identify secondary procedure codes that indicate APLs, but rather to illustrate the potential utility of this approach to expanding the definition of the APL PSI. To ascertain which patients may be identified using procedure codes in addition to hysterectomies, we first examined the distribution of patients by primary procedure in the APL PSI. Several primary procedures occurred at a high frequency and were used for this analysis.

For patients undergoing five principal procedures, Table 4 presents the proportion of cases not captured by the PSI. While it is impressive that bladder injuries from hysterectomies, bowel injuries from cholecystectomies, and spinal injuries from lumbar surgery are largely captured by the PSI, 19–27 percent of the events from these three primary procedures go undetected. Abdominal injuries due to lysis of peritoneal adhesions and nephroureterectomy are not captured well by the PSI, with approximately 50 percent of these events not identified. Examining five primary procedures, 238 cases that appear to be APLs but were not captured by the PSI were identified. The number of events captured by the PSI could be increased by approximately 6 percent if these events were added, and potentially more if additional primary procedures were analyzed.

Several of the PSIs are based on capturing E-code data, including the APL PSI. These codes are used to classify environmental events, circumstances, and other conditions as the cause of injury and other adverse effects. E-codes are critical for capturing information on the mechanism (e.g., motor vehicle traffic, fall, fire/burn, firearm, poisoning) and intent (e.g., unintentional, assault, suicide attempt) of injuries at the State and local levels. However not all States have been able to achieve a high level of E-coding in statewide hospital-based data systems, nor do all States' uniform billing committees require use of E-codes. Because of these limitations, it is especially important to explore alternative methods of identifying adverse events that do not rely on E-codes. The use of CSP 17, procedure-related perforation or laceration,[11] the AHRQ's experimental PSI, suture of laceration,[19] or the use of specific secondary procedure codes for select primary procedures are approaches to capturing these important adverse events without relying on the E-codes.

Conclusions

The AHRQ PSIs are based on the best available evidence regarding the use of administrative data to identify adverse events. AHRQ's work has improved the quality of the indicators, but any indicator based on secondary data will be subject to limitations. In this analysis, the definition of a particular PSI has been closely examined and several methods of improving the indicator have been identified. The revised indicator can be used on the same datasets that are appropriate for the original indicator. Our intent was to recommend changes that could be easily implemented without requiring any additional data to the standard inpatient discharge dataset. We look forward to future efforts to use administrative data to more accurately and completely ascertain the prevalence of iatrogenic adverse events.

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